NOV 5 2002

Attachment 4

K023586

510(k) Summary

Prepared: October 19, 2002

Submitter:

Company Name:	Canon U.S.A., Inc. (U.S. agent/official correspondent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Sheila Driscoll, Senior Product Safety Engineer
Phone Number:	(516) 328-5602
Fax number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-11 DR-ER add. version
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-11
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	K981556

Description Of Device:

The Canon X-ray digital camera model CXDI-11 DR-ER add. version is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon X-ray Digital Camera CXDI-11 DR-ER add. version is substantially equivalent to the Canon X-ray Digital Camera CXDI-11.

Intended Use:

Canon X-ray digital camera CXDI-11/ CXDI-11 DR-ER add. version provide digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

510(k) Summary

Prepared: October 19, 2002

Submitter:

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Contact Person:	Sheila Driscoll, Senior Product Safety Engineer
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Fax number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-22 DR-ER add. version
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-22
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	K992547

Description Of Device:

The Canon X-ray digital camera model CXDI-22 DR-ER add. version is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon X-ray Digital Camera CXDI-22 DR-ER add. version is substantially equivalent to the Canon X-ray Digital Camera CXDI-22.

Intended Use:

Canon X-ray digital camera CXDI-22/ CXDI-22 DR-ER add. version provide digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

510(k) Summary

Prepared: October 19, 2002

Submitter:

Company Name:	Canon U.S.A., Inc. (U.S. agent/official correspondent for Canon Inc.)
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Contact Person:	Sheila Driscoll, Senior Product Safety Engineer
Phone Number:	(516) 328-5602
Fax number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-31 DR-ER add. version
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-31
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	K003689

Description Of Device:

The Canon X-ray digital camera model CXDI-31 DR-ER add. version is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon X-ray Digital Camera CXDI-31 DR-ER add. version is substantially equivalent to the Canon X-ray Digital Camera CXDI-31.

Intended Use:

Canon X-ray digital camera CXDI-31/ CXDI-31 DR-ER add. version provide digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Sheila Driscoll
Senior Product Safety Engineer
Canon U.S.A., Inc.
One Canon Plaza
LAKE SUCCESS NY 11042-1198

AUG 23 2013

Re: K023586
Trade/Device Name: DR-ER Version of Canon X-ray Digital Cameras
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 23, 2002
Received: October 25, 2002

Dear Ms. Driscoll:

This letter corrects our substantially equivalent letter of November 5, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number
(if known) K023586

Device Name

DR-ER Version of Canon X-ray Digital Cameras

Indications for Use

The DR-ER version of Canon's X-ray Digital Cameras provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023586